Title: **COMPARISON OF SUBJECTIVE AND PHYSICAL FUNCTION OUTCOMES USING AXILLARY CRUTCHES AND A "HANDS-FREE CRUTCH," IN COMPARISON TO NO CRUTCH, FOR MOBILITY**

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Original Scientific Investigation

1. **Purpose/Hypothesis:**
   Physical therapists regularly give advice on assisted devices (AD) for gait. One limitation of axillary crutches (AC) is the inability to use your hands while using the AD. A new FDA approved "hands-free" crutch (HFC) may be used as an AD for gait instead; it is strapped to the leg, making the hands available. The HFC has not been compared for functional or subjective performance. The purpose of this study was to investigate functional and subjective outcomes for walking with the standard AC and the HFC, in comparison to no AD. We hypothesized that either AD would be significantly impaired compared to no AD, there would be no differences between the AD, and that individuals would prefer the HFC.
2. **Subjects:**
   Seventeen subjects (15 females, age: 27.7±1.7 years) that were physically active and had prior experience using an AD (per the requirements of our Institutional Review Board) participated.
3. **Methods and Materials:**
   Baseline testing included performing the 6-minute-walk-test (6MWT), Stair-Climbing-Test (SCT), and Timed-Up-and-Go Test (TUG). Following testing, subjects were randomized to either the AC or the HFC, and were fitted and trained on walking, stair climbing, and transfers. Subjects took the AD home to complete training while using the device, completed an activity log, and returned for follow-up testing using the device. All then repeated the training and testing procedure with the remaining AD. Following all functional testing, subjects completed a subjective Likert scale questionnaire for AD preference to assess subject preference for the AD during the 6MWT, SCT, and TUG. Potential differences between no AD, AC, and HFC were examined using a repeated ANOVA. Likert scores were not subject to statistical analysis because of the dichotomous distribution of the ratings.
4. **Results:**
   Significant main effects were found for the 6MWT, SCT, and TUG ($p<0.001$). For the 6MWT, subjects walked significantly ***farther*** without an AD (2147±179 feet) than the other conditions ($p<0.001$), but not significantly farther with the AC (1279.1±242 feet) than the HFC (1269.7±254 feet; $p=0.851$). During the SCT, subjects walked significantly ***faster*** without an AD (8.89±1.28 seconds) than the other conditions ($p<0.001$), and trended towards being ***faster*** with the HFC (27.77±5.95 seconds) than the AC (29.52±5.42 seconds; $p=0.081$). In the TUG, subjects walked significantly ***faster*** without an AD (5.73±0.51 seconds) than the other conditions ($p<0.001$), and were significantly ***faster*** with the HFC (10.11±1.98 seconds) than the AC (10.76±1.50 seconds; $p=0.048$). The majority

of subjects preferred the HFC over the AC for both the 6MWT and the SCT, while the preference for the TUG was mixed.

5. **Conclusions:**
   Functional outcomes were better using the HFC in comparison to the more standard AC while performing clinical outcome measures of activity. Any potential differences between the two AD should be interpreted cautiously, as they may not exceed the minimal detectable change for these tests. Subjective preference was mixed, however, the majority of subjects preferred the HFC while performing the SCT and 6MWT.

6. **Scientific/Clinical Merit/Significance:**
   Therapists may consider using the HFC as an AD in cases where endurance or stair ambulation is hindered using AC.